

jc952 U.S. PRO
10/24/00

PATENT

Preliminary Classification:
Proposed Class:
Subclass:

U.S. PTO
09/695562



10/24/00

No fee



1. **Type of Application**

This transmittal is for an original (nonprovisional) application.

2. **Papers Enclosed**

A. Required for filing date under 37 C.F.R. 1.53(b) (Regular) or 37 C.F.R. 1.153 (Design) Application

7 Page(s) of Specification

2 Page(s) of Claims

1 Sheet(s) of Drawing(s)--Formal

B. Other Papers Enclosed

1 Page(s) of abstract

3. **Additional Papers Enclosed**

Amendment to claims

Cancel in this applications claims 1 before calculating the filing fee.

Add the claims shown on the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims.)

Preliminary Amendment

Information Disclosure Statement (37 C.F.R. 1.98)

Replacement Claim Pages

4. **Declaration or Oath**

Not Enclosed.

Application is made by a person authorized under 37 C.F.R. Section 1.41(c) on behalf of all of the above-named inventors.

5. **Inventorship Statement**

The inventorship for all the claims in this application is the same.

0959562-103400

6. **Language**

English

7. **Certified Copy**

Certified copy of application:

<u>Country</u>	<u>Application Number</u>	<u>Filed</u>
Germany	199 51 477.1	10/26/1999

from which priority is claimed is attached.

8. **Fee Calculation (37 C.F.R. Section 1.16)**

Regular Application

CLAIMS AS FILED					
Claims	Number Filed	Basic Fee Allowance	Number Extra	Rate	Basic Fee 37 CFR 1.16(a) \$710.00
Total Claims (37 CFR 1.16(c))	15	- 20 =	0 x	\$18.00	\$0.00
Independent Claims (37 CFR 1.16(b))	1	- 3 =	0 x	\$80.00	\$0.00
Multiple Dependent Claim(s), if any (37 CFR 1.16(d))			+	\$270.00	\$0.00

Amendment deleting multiple-dependencies is enclosed.

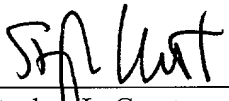
Filing Fee Calculation \$710.00

9. **Fee Payment Being Made at This Time**

Not Enclosed

Date: 10/24/00

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Schaldach, et. al.

Examiner:

Ser. No.:

Art Group:

Title: STENT

Filed: 24 October 2000

Date: 24 October 2000

PRELIMINARY AMENDMENT

- 1) This Preliminary Amendment is filed contemporaneously with the filing of a U.S. Patent Application claiming priority from an application filed in Germany as 199 51 477.1 on 26 October 1999. The fees for the claims should be calculated based on the claims remaining after the entry of this Preliminary Amendment, which results in 15 total and 1 independent claim.

Consistent with the modifications to 37 CFR §1.121, the applicant has provided the amended claims in a clean form on the enclosed replacement sheets.

- 2) Amendments to the Disclosure

None at this time.

- 3) Amendments to the Figures

None at this time.

- 4) Amendments to the Claims

After the heading "CLAIMS" and before the beginning of the claims, please insert the words: --

What is claimed is: --

Please cancel claim 1, without bias or prejudice:

1. (canceled) A stent, in particular a coronary stent, having a coating (6, 18), characterised in that the coating (6, 18) is of an irregular nature.

Please amend the claims as follows:

2. (amended) A stent as set forth in claim 13 [1] wherein the coating [(6, 18)] is irregular in respect of its thickness.
3. (amended) A stent as set forth in claim 2 wherein the coating [(6, 18)] is completely missing at at least one location on the surface [(4)] of the stent.
4. (amended) A stent as set forth in claim 3 wherein the coating [(6, 18)] is interrupted in a grid-like pattern.
5. (amended) A stent as set forth in claim 13 [one of the preceding claims] wherein the coating [(6, 18)] is provided in the form of coating islands [(18)] on the surface of the stent.
6. (amended) A stent as set forth in claim 5 wherein the coating islands [(18)] are of a substantially round configuration.
7. (amended) A stent as set forth in claim 5 [one of claims 5 and 6] wherein the coating islands [(18)] are all of substantially the same size.
8. (amended) A stent as set forth in claim 5 [one of claims 5 through 7] wherein the coating islands [(18)] in regions [(12, 14, 16)] involving a greater degree of local stretching of the stent surface [(4)] upon stretching of the stent are arranged at a greater mutual spacing than in regions [(8, 10)] involving a lesser degree of local stretching of the stent surface.
9. (amended) A stent as set forth in claim 5 [one of claims 5, 6 and 8] wherein the coating islands [(18)] in regions [(12, 14, 16)] involving a greater degree of local stretching of the stent surface [(4)] upon stretching of the stent are smaller than in regions [(8, 10)] involving a lesser degree of local stretching of the stent surface.

10. (amended) A stent as set forth in claim 9 wherein the mutual spacings of the coating islands [(18)] are substantially the same everywhere.
11. (amended) A stent as set forth in claim 13 [one of the preceding claims] wherein the coating [(6, 18)] comprises biocompatible material.
12. (amended) A stent as set forth in claim 13 [one of the preceding claims] wherein the coating [contains] comprises at least one member selected from a group consisting of: amorphous silicon carbide [(a-SiC)], hydrogenated amorphous silicon carbide [(a-SiC:H)] and [and/or] gold.


Please insert the following new claims:

13. (new) A stent having a surface with a coating, characterised in that the coating is formed irregularly on the surface.
14. (new) A stent as set forth in claim 6 wherein the coating islands are all of substantially the same size.
15. (new) A stent as set forth in claim 6 wherein the coating islands in regions involving a greater degree of local stretching of the stent surface upon stretching of the stent are arranged at a greater mutual spacing than in regions involving a lesser degree of local stretching of the stent surface.
16. (new) A stent as set forth in claim 6 wherein the coating islands in regions involving a greater degree of local stretching of the stent surface upon stretching of the stent are smaller than in regions involving a lesser degree of local stretching of the stent surface.

REMARKS

The above claims have been amended to more closely correspond them to United States claiming practice, namely, by removing multiple dependencies, especially improper multiple

Respectfully submitted,


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CLAIMS

What is claimed is:

1. (canceled)
2. (amended) A stent as set forth in claim 13 wherein the coating is irregular in respect of its thickness.
3. (amended) A stent as set forth in claim 2 wherein the coating is completely missing at at least one location on the surface of the stent.
4. (amended) A stent as set forth in claim 3 wherein the coating is interrupted in a grid-like pattern.
5. (amended) A stent as set forth in claim 13 wherein the coating is provided in the form of coating islands on the surface of the stent.
6. (amended) A stent as set forth in claim 5 wherein the coating islands are of a substantially round configuration.
7. (amended) A stent as set forth in claim 5 wherein the coating islands are all of substantially the same size.
8. (amended) A stent as set forth in claim 5 wherein the coating islands in regions involving a greater degree of local stretching of the stent surface upon stretching of the stent are arranged at a greater mutual spacing than in regions involving a lesser degree of local stretching of the stent surface.
9. (amended) A stent as set forth in claim 5 wherein the coating islands in regions involving a greater degree of local stretching of the stent surface upon stretching of the stent are smaller than in regions involving a lesser degree of local stretching of the stent surface.
10. (amended) A stent as set forth in claim 9 wherein the mutual spacings of the coating islands are substantially the same everywhere.

11. (amended) A stent as set forth in claim 13 wherein the coating comprises biocompatible material.
12. (amended) A stent as set forth in claim 13 wherein the coating comprises at least one member selected from a group consisting of: amorphous silicon carbide, hydrogenated amorphous silicon carbide and gold.
13. (new) A stent having a surface with a coating, characterised in that the coating is formed irregularly on the surface.
14. (new) A stent as set forth in claim 6 wherein the coating islands are all of substantially the same size.
15. (new) A stent as set forth in claim 6 wherein the coating islands in regions involving a greater degree of local stretching of the stent surface upon stretching of the stent are arranged at a greater mutual spacing than in regions involving a lesser degree of local stretching of the stent surface.
16. (new) A stent as set forth in claim 6 wherein the coating islands in regions involving a greater degree of local stretching of the stent surface upon stretching of the stent are smaller than in regions involving a lesser degree of local stretching of the stent surface.

5

Berlin 29th August 2000
Our ref: BB1143 JVO/js
Applicants/proprietors: BIOTRONIK Mess- und Therapiegeräte
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10 Office ref: New application

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Stent

20 The invention concerns a stent having a coating.

Stents are known from the state of the art in many different forms. Stents are used inter alia in connection with percutaneous transluminal angioplasty (PCTA, Percutaneous Transluminal Balloon Angioplasty) in
25 vascular surgery of the heart. Stents however can also serve to dilate other openings in the body or to keep such openings in a dilated condition. That medical procedure is initially preceded by determining the location of the constriction in a coronary blood vessel. A so-called angioplasty balloon is then moved in the artery which has the constriction, the so-called stenosis,
30 to the location of the stenosis where it is inflated. Due to the radially outwardly directed force of the inflated balloon the constriction is dilated and in the optimum case the original passage cross-section of the previously constricted artery is restored.

Besides successful dilation of the vessel however side-effects can occur, which include local splits in the artery, disintegration effects and projections of plate portions and flakes into the lumen of the artery so that, in spite of the dilation effect, blockage of the vessel can still occur. In addition it is possible that a stenosis can re-occur due to the vessel wall elastically springing back and/or due to the growth of the intima of the vessel. Statistically, that occurs within six months in the case of over 30% of the patients who were treated with PCTA.

In order now immediately after dilation of the blood vessel to ensure a relatively smooth inside wall surface for the vessel and to be able to avoid renewed stenosis, stents were developed. Those small tubes serve inter alia in conjunction with PCTA to maintain the vessel flow cross-section which is produced by balloon angioplasty, in order thereby to ensure long-term success with the PCTA procedure.

The success of such so-called stenting also depends inter alia on how quickly blood particles are deposited on the stent when fitted into the vessel. For, the more rapidly blood particles are deposited on the stent surfaces, the more rapidly vessel constrictions recur in the region of the stents, by virtue of such deposits. It is therefore desirable to provide stent surfaces which make it difficult for the blood particles to be deposited on the surface of the stent and thus constrict the flow cross-section of the blood vessel provided with a stent.

In order to prevent deposits of that kind or to at least make it more difficult for them to form, it is therefore known from the state of the art for the surfaces of the stents to be coated with a material which makes it more difficult for blood particles to be deposited on the stent surface, that is to say, on that coating.

When a stent provided with such a coating is now radially expanded in the blood vessel, coatings of that kind are also expanded therewith. In that

respect it has been found that those coatings in the state of the art are only capable to a limited extent of following the corresponding expansion of the stent. As a result those stent coatings chip off the stent surface if expansion of the stent and therewith the tension produced in the coating
5 become excessive.

Accordingly, the object of the invention is to avoid the above-indicated disadvantages and to provide a stent of the kind set forth in the opening part of this specification, whose coating does not chip off the stent even
10 upon stretching of the stent.

In accordance with the invention in a stent of the kind set forth in the opening part of this specification that object is attained in that the coating is formed irregularly on the stent surface.
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The advantages of the present invention are in particular that the irregularly formed coating means that the coating can be adapted to meet the prevailing demands in respect of the coating. For, upon expansion of the stent, the fact that the stent is stretched to different degrees in various regions also involves stretching to different degrees of the coating disposed
20 in those regions. Thus, by virtue of the irregularly formed coating, the coating can be thinner at locations where the stent experiences a great degree of stretching, than at locations which involve a lesser degree of stretching of the stent when the stent is inserted into a blood vessel. It is
25 thus possible by virtue of the invention to provide that the coating does not chip or peel off as in its thinner regions it can still follow even extreme local stretching phenomena.

In a further preferred embodiment of the invention the coating is
30 completely removed at at least one location on the surface of the stent. That location is preferably a location involving elevated local stretching of the stent upon expansion of the stent. When the stent has a coating of that kind which is not of a continuous or complete nature therefore there are

formed between individual coated regions gaps or joins in which a length compensation effect can occur between the portions of the coating so that the stresses which occur in the continuously closed coating in the state of the art can be reduced. That therefore provides that the coating cannot
5 chip or flake off at that location of extreme local stretching of the stent as the coating is not provided there from the outset. In that respect each gap or join between the individual coated regions delimits a region whose maximum dimensions are afforded by the maximum stretching of the stent which occurs at that location. In adjacent relationship to that free location,
10 that is to say in regions in which the local stretching effect would not result in the coating chipping off, the coating is again present. In that respect the coating may involve a thickness gradient so that the coating becomes uniformly thicker for example from the location at which there is no coating to a location at which no local stretching occurs upon expansion of the
15 stent. That provides for a smooth and gentle surface profile for the coating on the stent.

In a further preferred embodiment of the invention the coating is arranged in a pattern-like or grid-like configuration. In another embodiment of the
20 invention that grid configuration or patterning can also relate to the thickness of the coating. In both cases however this ensures in the patterned configuration that the stent has in a regular fashion thereon coating regions which can withstand even relatively high local stretching effects without chipping off. In this embodiment therefore it is not
25 absolutely necessary to pay attention to precisely locating locations with a high level of local stretching; on the contrary, by means of a coating which is patterned overall in that way it is possible to prevent the coating from chipping off from the outset at any location on the stent. For, in this
30 embodiment, the coating portions which are applied to the stent in a grid-like or pattern configuration are preferably so small that they do not chip off at any event when the stent is subjected to stretching. A stent which is coated in a grid-like or patterned configuration in that way is therefore inherently immune to the coating chipping off.

In a further preferred embodiment of the present stent coating the coating is arranged in the form of coating islands on the surface of the stent. These coating islands which in a further preferred feature are of a circular configuration best embody the success according to the invention. For, coating islands of that kind can simply be applied in uniform form and at the same time ensure that there is a uniform distribution of the stretch forces acting on the coating in the coating island itself. That avoids stretch effect peaks in the coating itself; thus, in the case of a round coating island of that kind, the stretch loading in respect of the coating island within the coating island is substantially more uniform and regular than in the case of islands which are of an irregular shape.

The invention can also be adapted to various requirements in respect of the stent. Thus, depending on the respective stent structure involved, it is advantageous if all coating islands are of substantially equal size. In this embodiment it is then further preferred if the coating islands in regions involving a greater degree of local stretching of the stent surface upon stretching of the stent are arranged at a greater mutual spacing than in regions involving a lesser degree of local stretching of the stent surface. In this embodiment therefore, with coating islands of equal size, the different degrees of local stretching of the stent are taken into consideration by virtue of different spacings of the coating islands on the surface of the stent.

In other stent structures, it has proven to be advantageous if the mutual spacings of the coating islands are of equal size substantially everywhere on the surface of the stent. In this embodiment, adaptation of the coating to the different degree of stretching of the stent is effected by the coating islands in the regions involving a greater degree of local stretching of the stent surface being smaller than in regions involving a lesser degree of local stretching of the stent surface. In this embodiment therefore adaptation of

In a further particularly preferred embodiment of the present invention the coating is made of biocompatible material. That provides for optimum medical compatibility of the stent.

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The coating 6 is applied to the surface 4 of the wire 2 in different densities in accordance with the differing stretching of the regions 8 through 6. That differing density is achieved in that the individual coating islands 18 of the coating 6, which are each of a circular configuration, are arranged at differing spacings relative to each other on the surface 4. Thus, those

CLAIMS

1. A stent, in particular a coronary stent, having a coating (6, 18), characterised in that the coating (6, 18) is of an irregular nature.
2. A stent as set forth in claim 1 wherein the coating (6, 18) is irregular in respect of its thickness.
3. A stent as set forth in claim 2 wherein the coating (6, 18) is completely missing at at least one location on the surface (4) of the stent.
4. A stent as set forth in claim 3 wherein the coating (6, 18) is interrupted in a grid-like pattern.
5. A stent as set forth in one of the preceding claims wherein the coating (6, 18) is provided in the form of coating islands (18) on the surface of the stent.
6. A stent as set forth in claim 5 wherein the coating islands (18) are of a substantially round configuration.
7. A stent as set forth in one of claims 5 and 6 wherein the coating islands (18) are all of substantially the same size.
8. A stent as set forth in one of claims 5 through 7 wherein the coating islands (18) in regions (12, 14, 16) involving a greater degree of local stretching of the stent surface (4) upon stretching of the stent are arranged at a greater mutual spacing than in regions (8, 10) involving a lesser degree of local stretching of the stent surface (4).
9. A stent as set forth in one of claims 5, 6 and 8 wherein the coating islands (18) in regions (12, 14, 16) involving a greater degree of local

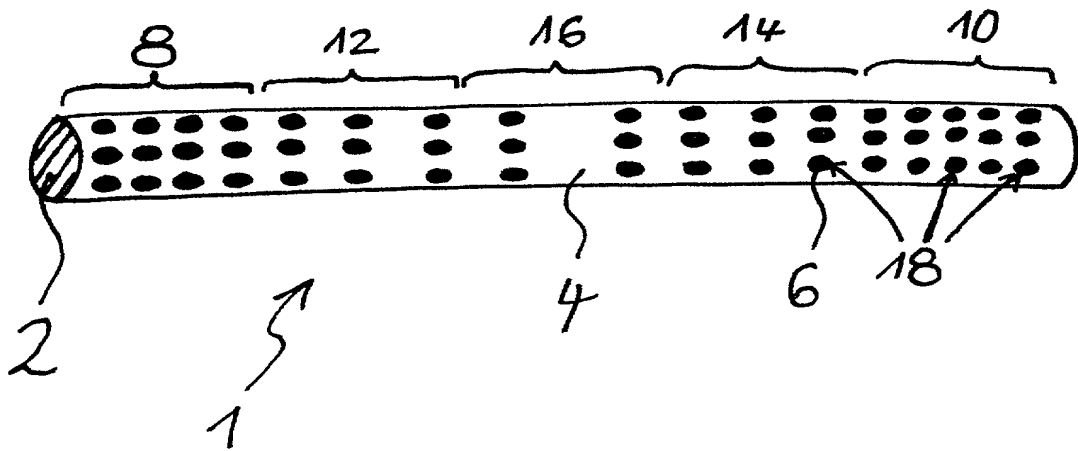
Variable	Mean	Standard Deviation	Minimum	Maximum
Age	34.5	10.2	22	55
Gender	0.5	0.5	0	1
Marital Status	0.6	0.5	0	1
Education	12.5	1.5	10	16
Income	3500	1500	1000	8000
Health	0.8	0.2	0	1
Smoking	0.3	0.5	0	1
Alcohol	0.2	0.4	0	1
Exercise	0.4	0.5	0	1
Stress	0.6	0.5	0	1
Sleep	0.7	0.3	0	1
Work	0.8	0.2	0	1
Family	0.9	0.1	0	1
Friends	0.7	0.4	0	1
Hobbies	0.6	0.5	0	1
Travel	0.5	0.5	0	1
Volunteering	0.4	0.5	0	1
Religion	0.3	0.5	0	1
Politics	0.2	0.4	0	1
Art	0.1	0.3	0	1
Music	0.2	0.4	0	1
Gardening	0.3	0.5	0	1
Reading	0.4	0.5	0	1
Writing	0.3	0.5	0	1
Cooking	0.4	0.5	0	1
Shopping	0.5	0.5	0	1
Driving	0.6	0.5	0	1
Swimming	0.3	0.5	0	1
Fishing	0.2	0.4	0	1
Hiking	0.4	0.5	0	1
Cycling	0.3	0.5	0	1
Yoga	0.2	0.4	0	1
Meditation	0.1	0.3	0	1
Journaling	0.2	0.4	0	1
Photography	0.3	0.5	0	1
Dancing	0.2	0.4	0	1
Golfing	0.1	0.3	0	1
Tennis	0.2	0.4	0	1
Baseball	0.1	0.3	0	1
Soccer	0.2	0.4	0	1
Boxing	0.1	0.3	0	1
Weightlifting	0.2	0.4	0	1
Cardio	0.3	0.5	0	1
Strength Training	0.2	0.4	0	1
Stretching	0.3	0.5	0	1
Massage	0.2	0.4	0	1
Acupuncture	0.1	0.3	0	1
Chiropractic	0.2	0.4	0	1
Herbal Medicine	0.1	0.3	0	1
Meditation	0.2	0.4	0	1
Yoga	0.3	0.5	0	1
Journaling	0.2	0.4	0	1
Photography	0.3	0.5	0	1
Dancing	0.2	0.4	0	1
Golfing	0.1	0.3	0	1
Tennis	0.2	0.4	0	1
Baseball	0.1	0.3	0	1
Soccer	0.2	0.4	0	1
Boxing	0.1	0.3	0	1
Weightlifting	0.2	0.4	0	1
Cardio	0.3	0.5	0	1
Strength Training	0.2	0.4	0	1
Stretching	0.3	0.5	0	1
Massage	0.2	0.4	0	1
Acupuncture	0.1	0.3	0	1
Chiropractic	0.2	0.4	0	1
Herbal Medicine	0.1	0.3	0	1

- | Variable | Mean | Standard Deviation | Minimum | Maximum |
|-------------------|------|--------------------|---------|---------|
| Age | 34.5 | 10.2 | 22 | 55 |
| Gender | 0.5 | 0.5 | 0 | 1 |
| Marital Status | 0.6 | 0.5 | 0 | 1 |
| Education | 12.5 | 1.5 | 10 | 16 |
| Income | 3500 | 1500 | 1000 | 8000 |
| Health | 0.8 | 0.2 | 0 | 1 |
| Smoking | 0.3 | 0.5 | 0 | 1 |
| Alcohol | 0.2 | 0.4 | 0 | 1 |
| Exercise | 0.4 | 0.5 | 0 | 1 |
| Stress | 0.6 | 0.5 | 0 | 1 |
| Sleep | 0.7 | 0.3 | 0 | 1 |
| Work | 0.8 | 0.2 | 0 | 1 |
| Family | 0.9 | 0.1 | 0 | 1 |
| Friends | 0.7 | 0.4 | 0 | 1 |
| Hobbies | 0.6 | 0.5 | 0 | 1 |
| Travel | 0.5 | 0.5 | 0 | 1 |
| Volunteering | 0.4 | 0.5 | 0 | 1 |
| Religion | 0.3 | 0.5 | 0 | 1 |
| Politics | 0.2 | 0.4 | 0 | 1 |
| Art | 0.1 | 0.3 | 0 | 1 |
| Music | 0.2 | 0.4 | 0 | 1 |
| Gardening | 0.3 | 0.5 | 0 | 1 |
| Reading | 0.4 | 0.5 | 0 | 1 |
| Writing | 0.3 | 0.5 | 0 | 1 |
| Cooking | 0.4 | 0.5 | 0 | 1 |
| Shopping | 0.5 | 0.5 | 0 | 1 |
| Driving | 0.6 | 0.5 | 0 | 1 |
| Swimming | 0.3 | 0.5 | 0 | 1 |
| Fishing | 0.2 | 0.4 | 0 | 1 |
| Hiking | 0.4 | 0.5 | 0 | 1 |
| Cycling | 0.3 | 0.5 | 0 | 1 |
| Yoga | 0.2 | 0.4 | 0 | 1 |
| Meditation | 0.1 | 0.3 | 0 | 1 |
| Journaling | 0.2 | 0.4 | 0 | 1 |
| Photography | 0.3 | 0.5 | 0 | 1 |
| Dancing | 0.2 | 0.4 | 0 | 1 |
| Golfing | 0.1 | 0.3 | 0 | 1 |
| Tennis | 0.2 | 0.4 | 0 | 1 |
| Baseball | 0.1 | 0.3 | 0 | 1 |
| Soccer | 0.2 | 0.4 | 0 | 1 |
| Boxing | 0.1 | 0.3 | 0 | 1 |
| Weightlifting | 0.2 | 0.4 | 0 | 1 |
| Cardio | 0.3 | 0.5 | 0 | 1 |
| Strength Training | 0.2 | 0.4 | 0 | 1 |
| Stretching | 0.3 | 0.5 | 0 | 1 |
| Massage | 0.2 | 0.4 | 0 | 1 |
| Acupuncture | 0.1 | 0.3 | 0 | 1 |
| Chiropractic | 0.2 | 0.4 | 0 | 1 |
| Herbal Medicine | 0.1 | 0.3 | 0 | 1 |
| Meditation | 0.2 | 0.4 | 0 | 1 |
| Yoga | 0.3 | 0.5 | 0 | 1 |
| Journaling | 0.2 | 0.4 | 0 | 1 |
| Photography | 0.3 | 0.5 | 0 | 1 |
| Dancing | 0.2 | 0.4 | 0 | 1 |
| Golfing | 0.1 | 0.3 | 0 | 1 |
| Tennis | 0.2 | 0.4 | 0 | 1 |
| Baseball | 0.1 | 0.3 | 0 | 1 |
| Soccer | 0.2 | 0.4 | 0 | 1 |
| Boxing | 0.1 | 0.3 | 0 | 1 |
| Weightlifting | 0.2 | 0.4 | 0 | 1 |
| Cardio | 0.3 | 0.5 | 0 | 1 |
| Strength Training | 0.2 | 0.4 | 0 | 1 |
| Stretching | 0.3 | 0.5 | 0 | 1 |
| Massage | 0.2 | 0.4 | 0 | 1 |
| Acupuncture | 0.1 | 0.3 | 0 | 1 |
| Chiropractic | 0.2 | 0.4 | 0 | 1 |
| Herbal Medicine | 0.1 | 0.3 | 0 | 1 |

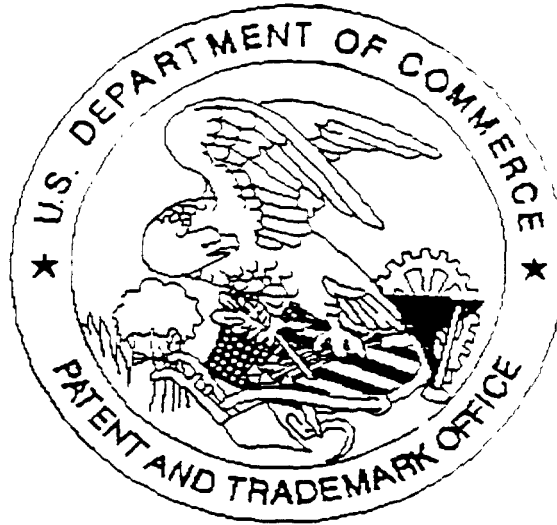
Abstract

The invention concerns a stent, in particular a coronary stent, having a coating. The coronary stent according to the invention is distinguished in that the coating is of an irregular and in particular grid-like patterned configuration.

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United States Patent & Trademark Office
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SCANNED, # _____

Application deficiencies were found during scanning:

☒ Page(s) 5-14 of 14 of Transmittal were not present:
for scanning. (Document title)

☐ Page(s) _____ of _____ were not present:
for scanning. (Document title)

☐ Scanned copy is best available.